

REMARKS

Claims 22-42 were pending in the application. Claims 22, 24, 25 and 27-41 have been amended and claims 23 and 26 have been cancelled. New claims 43 and 44 have been added. Thus, upon entry of this amendment, claims 22, 24, 25 and 27-44 will remain pending in the application.

The limitations of cancelled claim 23 have been incorporated into claim 22. To better clarify the precise percentage ranges being claimed, cancelled 26 has been rewritten as two separate claims, claims 43 and 44.

No new matter has been added to the application. Any amendments to and/or cancellation of the claims was done solely for the purpose of expediting prosecution of the present application. Applicants reserve the right to pursue the subject matter of the claims as originally filed in this or a separate application(s).

Information Disclosure Statement

An information disclosure statement is enclosed herewith to address the non-compliant information disclosure statement filed on February 25, 2004.

Objections to the Drawings

The Examiner has objected to the word “Trise2” in Figure 2.

Applicants respectfully submit that “Trise2” would have been recognized by the skilled artisan as an obvious contraction of “Temperature Rise 2”. However, to expedite prosecution, Figure 2 has been amended to recite “Temperature Rise 2” instead of “Trise2”.

Objections to the Specification and Abstract

To address the objections, Applicant submits herewith a substitute Specification and a new Abstract. No new matter is added.

Objections to the Claims

The claims have been amended to correct the informalities objected to by the Examiner.

Rejection of Claims 25 and 26 Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 25 and 26 under 35 U.S.C. §112, first paragraph. Specifically the Examiner alleges that the specification “does not disclose how the data is weighted by type that produces the order and percentages of weighted data.”

Applicants respectfully traverse this rejection. Claim 26 has been canceled. Accordingly, this rejection is rendered moot with respect to this claim. With respect to claim 25 and new claims 43 and 44, Applicants respectfully point out to the Examiner that the specification, at page 8, line 5 to page 9 line 8 provides a full disclosure of how the data are weighted by type. Indeed, this disclosure more than satisfies the written description requirement of 35 U.S.C. § 112. Accordingly, Applicants respectfully request that the rejection of claim 25 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Rejection of Claims 23-26, 32, 36 and 41 Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 23-26 under 35 U.S.C. §112, second paragraph as failing to distinctly point out the invention as a result of improper claim dependencies.

In response, claims 23 and 26 have been cancelled and claims 24 and 25 have been amended to depend from claim 22. Accordingly, this rejection should now be moot.

The Examiner has rejected claims 32, 36 and 41 as being indefinite due to the presence of the phrases “for example”, “e.g.” and “such as” respectively.

In response, claims 32, 36 and 41 have been amended to remove the above-mentioned phrases. Accordingly, this rejection should now be moot.

Rejection of Claims 22-27, 29 and 31-42 Under 35 U.S.C. § 103(a)

The Examiner has also rejected claims 22-27, 29 and 31-42 under 35 U.S.C. § 103(a) as being unpatentable over the US4465077 (Schneider) in view of US5572370 (Cho). Specifically, the Examiner relies on Schneider as teaching a method and apparatus which predicts when ovulation is to occur on the basis of basal body temperature, vaginal mucus change and past menstrual cycle history, and Cho as teaching a portable apparatus for determining the period of maximum fertility by measurement of saliva and comparing the patterns formed by the crystallized saliva on a specimen slide with standard patterns. The Examiner concludes that it

would have been obvious to combine Schneider and Cho to “provide a more convenient property of a biological fluid”.

Applicants respectfully traverse this rejection on the grounds that the Examiner has failed to establish a *prima facie* case of obviousness since Schneider and Cho either alone or in combination, fail to teach or suggest the claimed invention and further fail to provide the necessary motivation or reasonable expectation of success for the ordinarily skilled artisan to arrive at the presently claimed methods.

To establish a *prima facie* case of obviousness, it is necessary for the Examiner to apply a flexible teaching, suggestion, or motivation test to combine known elements in order to show that the combination is obvious. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). Importantly, the *KSR* Court noted that “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (*In re Kahn*, 441 F.3d 911,988 (CA Fed. 2006) cited with approval in *KSR*).

The Office Action has failed to point to any teaching in the cited references which would impel one of ordinary skill in the art to combine the teachings of the references in order to arrive at the presently claimed invention. It is established law that “[w]hile the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation (“TSM”) test, the Court acknowledged the importance of identifying ‘a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does’ in an obviousness determination.” *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007) (quoting *KSR*, 127 S. Ct. at 1731). Although the prior art reference, or references when combined, need not teach or suggest all of the claim limitations, a *reason* must be given why the differences between the prior art and the claimed limitation would have been obvious to one of skill in the art (see Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103, Federal Register, Vol. 72, No. 195).

The claims, as amended, are directed to a device for family planning or contraception, comprising a means for determining basal temperature, a means for input of the first day of the cycle, a means for input of the property of the saliva, a device for processing the data made available by the means, a memory device for storing at least some of the data made available and a display device, whereby the device for processing the data is designed such that a conclusion regarding the woman's fertility on any given day is determined as a function of at

least some of the data made available by each means and this conclusion can be displayed via the display device *and the data are weighted differently in determining the conclusion regarding the woman's fertility.*

Schneider describes a method and apparatus which predicts when ovulation is to occur on the basis of basal body temperature, vaginal mucus change and past menstrual cycle history. Schneider does not teach or suggest the measurement of the properties of the saliva, nor does this reference teach or suggest that *the data are weighted differently in determining the conclusion regarding the woman's fertility.*

The deficiency is not corrected by Cho which teaches a portable apparatus for determining the period of maximum fertility by measurement of saliva and comparing the patterns formed by the crystallized saliva on a specimen slide with standard patterns. Cho describes an apparatus which uses only one method. Cho fails to teach or suggest any combination of methods for determining fertility, or that fertility data should be *weighted differently in determining the conclusion regarding the woman's fertility.*

Moreover, there would have been no motivation for the skilled artisan to modify the methods of Schneider and Cho to arrive at the claimed invention. Indeed, Schneider and Cho teach that their respective methods are sufficiently accurate alone to predict the days of the woman's menstrual cycle during which she is most likely to be able to conceive. Accordingly, from a reading of the cited references, the skilled artisan would have concluded that no further innovation of the devices of Schneider or Cho was necessary. Hence, instead of providing motivation, the cited references implicitly teach away from arriving at the claimed device. Applicant's respectfully submit, that it is only through the benefit of hindsight afforded by the teachings of the instant specification that the skilled artisan would be motivated to modify the teachings of Schneider and Cho to arrive at the claimed invention.

For the foregoing reasons, the claimed methods are non-obvious over the teachings of Schneider and Cho, either alone or in combination. Accordingly, Applicants respectfully request that the rejection of claims 22, 24, 25, 27, 29 and 31-42 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Rejection of Claims 28 and 30 Under 35 U.S.C. § 103(a)

The Examiner has also rejected claims 28 and 30 under 35 U.S.C. § 103(a) as being unpatentable over the US4465077 (Schneider) in view of US5572370 (Cho) and US5657762

(Coley). As discussed above, the Examiner relies on the Examiner relies on Schneider as teaching a method and apparatus which predicts when ovulation is to occur on the basis of basal body temperature, vaginal mucus change and past menstrual cycle history, and Cho as teaching a portable apparatus for determining the period of maximum fertility by measurement of saliva and comparing the patterns formed by the crystallized saliva on a specimen slide with standard patterns. The Examiner further relies on Coley as teaching a display device that shows possible fertile days in red, possible infertile days in green, and transition days in yellow. The Examiner concludes that it would have been obvious to use the color indicators of Coley in the invention of Schneider as modified by Cho.

Applicants respectfully traverse this rejection on the grounds that the Examiner has failed to establish a *prima facie* case of obviousness since Schneider, Cho, or Coley either alone or in combination, fail to teach or suggest the claimed invention and further fail to provide the necessary motivation or reasonable expectation of success for the ordinarily skilled artisan to arrive at the presently claimed methods.

As mentioned above, Schneider and Cho fail to teach or suggest a device for family planning or contraception, comprising a means for determining basal temperature, a means for input of the first day of the cycle, a means for input of the property of the saliva, a device for processing the data made available by the means, a memory device for storing at least some of the data made available and a display device, whereby the device for processing the data is designed such that a conclusion regarding the woman's fertility on any given day is determined as a function of at least some of the data made available by each means and this conclusion can be displayed via the display device ***and the data are weighted differently in determining the conclusion regarding the woman's fertility.***

Coley fails to correct this deficiency. This reference teaches a display device that shows possible fertile days in red, possible infertile days in green, and transition days in yellow. Coley does not teach or suggest a device for family planning in which ***the data are weighted differently in determining the conclusion regarding the woman's fertility.*** Moreover, there would have been no motivation for the skilled artisan to modify the methods of Schneider, Cho or Coley to arrive at the claimed invention.

For the foregoing reasons, the claimed methods are non-obvious over the teachings of Schneider, Cho and Coley, either alone or in combination. Accordingly, Applicants respectfully

request that the rejection of claims 28 and 30 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

CONCLUSION

In view of the above amendment, Applicants believe the pending application is in condition for allowance. If a telephone conversation with Applicants' attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400. Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. FR4-002 from which the undersigned is authorized to draw.

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Respectfully submitted,

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